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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/995,304

11/27/2001

Robert H. Kraus JR.

S-94,769

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09/12/2006

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,304

Applicant(s)

KRAUS ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-14 is/are rejected.
7) ☒ Claim(s) 15-16 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on June 20, 2006 has been acknowledged and entered.

Claims 1-16 are pending.

Withdrawn Rejection(s)

Rejection under 112, 1st paragraph is withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Miltenyi (US 5,543,289).

Miltenyi teaches a process for conducting of high gradient magnetic separation (HGMS). Superior superparamagnetic particles, coated with a polymer such as a polysaccharide or polystyrene, can be prepared in uniform compositions with homogeneous magnetizations. The coating can be conjugated to specific binding moiety complementary to a biological material whose purification or separation is desired. Then magnetization of the particles is measured. Magnetization means the magnetic moment per volume of the magnetic particles. Identical magnetic field for all

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the particles in the mixture is imposed. The superparamagnetic particles range from 0.04 μm to 0.1 μm in size. (see claim 1). Target biological materials are proteins, cells, viruses, bacteria, yeasts, glycoproteins, etc. (see col. 9, lines 6-21). Any number of components in a biological mixture can be labeled with particles of differing magnetizations by treating each homogeneous composition of particles with a different specific binding moiety complementary to a chosen component of the mixture. Each component will then uniquely react with one representative composition of a particular magnetization. The labeled mixture, when subjected to HGMS results in a chromatographic pattern of components separated according to the magnetization of the particles with which they are conjugated. (see col. 11, lines 54-65). Miltenyi also teaches that the superparamagnetic particles can be subjected to HGMS at any stage of its preparation process-before or after coating and before or after size preparation. The prepared particles are applied to HGMS apparatus and fractionated according to magnetic susceptibility). This teaching would apply to the limitation of claim 3- passing the magnetic microspheres through a magnetic field prior to the initial separation stage.(see col. 7, lines 55-62). Coating of the polymeric material around the microcrystals is the same as imbedding and immobilizing microcrystals on the surface of or within an organic polymeric material or glass because the polymeric coating also attaches to the magnetic crystals through the reactive group. Miltenyi teaches that the superparamagnetic particles are subjected to HGMS at any stage of this preparation process-before or after coating and before or after size separation. The prepared particles are applied to the HGMS apparatus and fractionated according to

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magnetization (magnetic moments/magnetic susceptibility). (see col. 7, lines 56-65).

Magnetization is defined in col.6, line 40-col. 7, line 2 as magnetic moment. In one procedure the mixture is applied to the HGMS column, containing matrix, at a very high magnetic field strength so that virtually all of the particles are retained. The particles are then eluted by gradually reduction of the magnetic field across (second magnetic field) the column.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miltenyi (US 5,543,289) in view of McDevitt et al. (US 6,649,403).

Miltenyi has been discussed above.

However, Miltenyi fails to teach the magnetic particles are selected from the group consisting of iron-cobalt, iron-platinum and samarium-cobalt.

McDevitt teaches assay and system for rapid characterization of multi-analyte fluids using magnetic particles comprising of magnetic materials such as samarium-cobalt. (see col. 114, lines 28-46).

It would have been obvious to one of ordinary skills in the art to use the magnetic material such as samarium-cobalt as taught by McDevitt in the method of Miltenyi since samarium-cobalt can be incorporated in colloidal particles. Samarium-cobalt is a rare-earth magnetic material which exhibits maximum magnetic property.

Response to Arguments

Applicant's arguments filed on January 30, 2006 have been fully considered but they are not persuasive.

Regarding the rejection under 102(b) by Miltenyi, Applicants submit that Miltenyi does not teach that the magnetic microspheres pass through a chamber and a collector in which the magnetic microspheres are separated in the presence of second magnetic field.

Claim 1 recites that "sorting said distinct populations of magnetic microspheres containing different receptor agent-target species complexes by ***passing said magnetic microspheres through a magnetic field to a chamber and a collector,*** wherein said magnetic microspheres having different magnetic moments are separated in the presence of a second magnetic field according to their respective magnetic moments".

Miltenyi teaches that the magnetic microspheres are passed through a magnetic field to a chamber in which all magnetic particles are retained and then are eventually eluted from the chamber by gradual reduction of the magnetic field across the column. Fractions are collected at arbitrary intervals resulting in the preparation of a series of compositions each having a desired degree of homogeneity of magnetization (see col.

7, line 62-col. 8, line 2). The reduced magnetic field is considered as a second magnetic field because it is different than the first magnetic field.

Applicants also argue that Miltenyi does not teach separation of magnetic particles having different magnetic moments in the collector. Applicants submit that the magnetic particles of Miltenyi have uniform compositions with homogenous magnetizations.

Miltenyi teaches that a mixture of A and B can be separated by treating the mixture with compositions of particles with specific binding moieties for each with differing potential magnetizations. For example, the mixture is treated with particles conjugated to anti-A which have high magnetic susceptibility and particles conjugated to anti-B which have low magnetic susceptibility. The labeled mixture is then applied to the apparatus and a magnetic field strength sufficient to retain both A and B associated magnetic particles is supplied. In elution, the magnetic field strength or magnetization of the suspending fluid is altered so as to release particles which are associated with B (by a second magnetic field) but not those associated with A, thus eluting a clean separation. (see col. 11, lines 39-51).

Since Miltenyi still applies to the present invention, the 103 rejection still remains. No further discussion is necessary.

Allowable Subject Matter

- Claims 15-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
August 31, 2006


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